Congress of the United States

Washington, DC 20515

April 6, 1998

Donna Shalala
Secretary of Health and Human Services
Department of Health and Human Services
200 Independence Avenue, S. W.
Washington, DC 20201

Dear Madam Secretary:

This letter is intended to convey the spirit of the Pediatric Labeling Section (111) of the Food and Drug Modernization and Accountability Act of 1997 (FDAMA).

The underlying purpose of this section was to increase the amount of information regarding pediatric use of drugs in all children. While drugs marketed in the United States have been studied extensively in adults, it is estimated that four out of five of these drugs have not been tested for safety and efficacy nor approved for use in children. Medical and scientific opinion leaders are unanimous concerning the desirability for further information on the use of drugs in children. This legislation presents an opportunity to advance therapies for infants, children and adolescents in addition to adults.

The legislative intent of Congress was for the FDA to broadly interpret Section 111 to ensure that drugs from all therapeutic and preventive areas would be studied for pediatric indications and would be included in the list, and that the list be developed by various drug categories and prioritized by various factors. Furthermore, the intent of the definition "a drug may produce health benefits"was to be construed very broadly. A drug should meet this definition if it was intended for treatment of a disease, condition or indication which occurs in infants and children.

Section 111 recognizes that different types of studies, such as pharmacokinetic studies, may be sufficient to establish safety and effectiveness in children for diseases where extensive information about the disease is available and when the disease characteristics are similar to those in adults. Such studies can build on what is already known about a drug from studies in adults. When limited information is available regarding certain diseases in children, more extensive research must be required to adequately determine safety and efficacy and this research should be subject to the same clinical scrutiny required of adult clinical trials.

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The pediatric provisions of the FDAMA provide incentives for the pharmaceutical industry to spend the resources necessary to develop the infrastructure to conduct good clinical trials in children. If implemented properly this incentive will create a "Golden Age for Pediatric Medicine." We believe the children of this country, our nation's future, deserve no less.

Sincerely,

Congressman Mike Bilirakis

Congressman Jim Greenwood

Senator Mike DeWine

Senator Christopher Dodd

04-09-98-0056

use." This is clearly applicable to devices as well. Use of literature provides a means of broadening the uses of drugs and devices without unnecessary regulatory barriers. However, there seems to be an applicability question as it relates to devices that is different from drugs that needs to be addressed. Since drug patents limit competitive drugs during the active life of the patent, it is assumed that many of the drug studies are conducted on the subject drug independent of the drug sponsor. With medical devices, however, the availability of similar devices from more than one sponsor is common and literature based on one device may be applicable to others. FDA law limits FDA's ability to use PMA clinical data from one device sponsor to support the approval of a second. However, it is not clear whether those data once published cannot be used by a second sponsor. In principle, this should be a viable option given the criteria cited in the CDER/CBER documents but neither document addresses this issue specifically. This is clearly needed to ensure consistency and fairness.

Therefore, HIMA recommends that instead of adopting the CDER/CBER Draft Guidance, CDRH develop criteria on the acceptability of literature as the sole basis for approval that are directly applicable to devices. Like the corresponding section of the CDER/CBER document this should not require more than 1 or 2 pages.

Again, HIMA appreciates this opportunity to comment on this draft guidance document.

Sincerely,

Janet Trunzo

Janet Trunzo
Director
Technology & Regulatory Affairs

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